

EVALUATION OF INFRARED TYMPANIC
THERMOMETERS ON MILD HYPOTHERMIC
SUBJECTS AND IN COLD
ENVIRONMENTS



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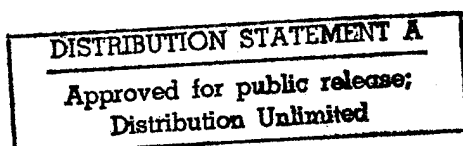
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ABSTRACT

The objective of the present study was to evaluate infrared tympanic thermometers (ITTs) on hypothermic subjects and under operationally relevant ambient conditions. Eight subjects (2 of them female) were cooled in 8-10°C water for 25 min on three occasions. Tympanic temperatures obtained with three brands of ITTs (Genius[®], Thermoscan[®], and Diatek[®]) were compared to three other core temperature estimates (esophageal, rectal, and ear canal) during the cold water immersions, and in a second series of experiments, to a temperature controlled target in cold air environments. On average, tympanic temperature (T_{ty}) measured from the three ITT instruments was $0.99 \pm 0.18^{\circ}\text{C}$ lower than the other core estimates. The differences between T_{ty} and each of the three core estimates were not different, but the three differences were larger for the Genius[®] ITT ($1.49 \pm 0.36^{\circ}\text{C}$) compared to the two other instruments ($0.63 \pm 0.21^{\circ}\text{C}$ for Diatek[®]; $0.63 \pm 0.20^{\circ}\text{C}$ for Thermoscan[®]). Furthermore, the ITT instruments failed to perform adequately in the cold. It was concluded that tympanic temperature measured by ITT instruments underestimates core temperature during hypothermia in humans, and the ITTs can not be used below their specified operating temperature.

EXECUTIVE SUMMARY

There is a requirement within the Canadian Forces Medical Service for better core temperature measurement in field applications. Infrared tympanic thermometers (ITTs) are appealing since they are non-invasive, easy to use, and give instantaneous readings.

The Director of Medical Operations for the Canadian Forces (DMO 3-2) requested that DCIEM evaluate infrared tympanic thermometers on hypothermic subjects and under operationally relevant ambient conditions.

Eight subjects (2 of them female) were cooled in 8-10°C water for 25 min on three occasions. Tympanic temperatures obtained with three brands of ITTs (Genius[®], Thermoscan[®], and Diatek[®]) were compared to three other core temperature estimates (esophageal, rectal, and ear canal) during the cold water immersions, and in a second series of experiments, to a temperature controlled target in cold air environments to define their validity and reliability in estimating core temperature of hypothermic victims in the field.

Tympanic temperatures measured with the three ITT instruments were almost 1°C lower than the other core estimates. The Genius[®] ITT provided tympanic temperature on average 0.5°C lower than the other two ITT instruments. Furthermore, ITT instruments failed to perform adequately in the cold. It was concluded that tympanic temperature measured by ITT instruments underestimates core temperature during hypothermia in humans, and the ITTs can not be used below their specified operating temperature.

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INTRODUCTION

There is a requirement within the Canadian Forces Medical Service for better core temperature measurement in field applications. Infrared Tympanic Thermometers (ITTs) are appealing since they are non-invasive, easy to use, and give instantaneous readings. Concerns exist, however, about the relationship of the observed tympanic temperature to other measures of deep body temperature (Ducharme et al., 1994) mainly on hypothermic patients. Furthermore, ITTs are specified by the manufacturer to operate within limited ambient temperature ranges. If ITTs are to be used by CF personnel in the field to assess and treat hypothermia, the likelihood that ambient temperatures will be within the specified operating range is very small. There is, therefore, a need to test the ITT instruments in a cold environment. DMO 3-2 tasked DCIEM to evaluate ITTs for field application.

The objectives of the present study was, therefore, to evaluate the accuracy and reliability of infrared tympanic thermometers to assess the thermal status of hypothermic patients in the field.

MATERIAL AND METHODS

Evaluation of ITT instruments on hypothermic subjects. Subjects. Eight healthy subjects (6 males and 2 females) volunteered to participate in the study. Their anthropometric characteristics are presented in Table 1. The percentage of body fat was estimated from the summation of four skinfold thicknesses (triceps, biceps, suprailiac and subscapular) measured by a Harpenden skinfold caliper (British Indicator, England) and calculated using the relationship developed by Durnin and Womersley (1974). The subject's ear canal characteristics (diameter, length, curvature, presence of cerumen and tympanic inflammation) were defined by an experienced otorhinolaryngologist using an otoscope. The health status of all subjects was assessed by a medical authority before participation. The subjects were fully informed of the procedures and possible risks of the study and their right to withdraw from the experiment at any time without prejudice. Written informed consent was obtained from all subjects before experimentation. The protocol was approved by Institutional Ethics Committees.

The subjects were asked to abstain from smoking and using any medication, drug, or other stimulant (including caffeine and alcohol) for at least 12 h before the experiments. All experiments were performed at the same time of the day for each subject.

Table 1. Anthropometric characteristics of the subjects

Subject #	Age, yr	Height, cm	Weight, kg	A _D m ²	Skinfold thickness mm	Body fat %
1*	23.1	172	67.3	1.79	113.8	38.3
2	37.2	183	82.0	2.04	62.6	23.9
3	30.6	176	82.5	1.99	38.6	18.8
4	31.2	181	72.0	1.92	27.8	15.3
5	25.2	184	75.5	1.97	40.3	16.5
6*	34.5	161	63.7	1.67	67.5	32.0
7	26.2	176	71.0	1.86	27.4	11.7
8	35.8	185	80.0	2.03	49.6	18.9
mean ± SE	30.5 ± 1.8	177 ± 3	74.3 ± 2.5	1.91 ± 0.05	53.5 ± 10.1	21.9 ± 3.2

A_D, DuBois surface area (Dubois and Dubois, 1916); skinfold thickness represent the summation at four sites: triceps, biceps, suprailiac and subscapular; *, female subject.

Core temperature of the subject was measured from 4 different sites: esophagus, rectum, left ear canal, and right tympanic membrane. Esophageal temperature (*T_{es}*) was measured with a type T thermocouple (Mon-a-therm General Purpose, Mallinckrodt Medical, St. Louis, MO) positioned at the level of the heart using the method of Mekjavik and Rempel (1990). Rectal temperature (*T_{re}*) was measured with a type T thermocouple (Mon-a-therm General Purpose, Mallinckrodt Medical, St. Louis, MO) positioned 15 cm into the rectum. Left ear canal temperature (*T_{ear}*) was measured with a fine type T thermocouple (Mon-a-therm Tympanic temperature sensor Mallinckrodt Medical, St. Louis, MO) positioned very close to the tympanic membrane. After touching the tympanic membrane, the probe was withdrawn just enough for the pain to disappear. The outside portion of the ear canal was filled with cotton and tape was used over the auricle to fix the probe and insulate the ear canal from the environment. Serial data from the thermocouples were acquired continuously during the immersions on an electrically isolated Macintosh IIfx computer and averaged every 30-s period. The process was controlled by a "virtual instrument" written using LabVIEW II graphical signal processing software (National

Instruments, Austin, TX). Right tympanic membrane temperature was measured with infrared tympanic thermometers from three manufacturers (FirstTemp Genius® model 3000A, Intelligent Medical Systems, CA, USA; Thermoscan® model IR-1, Thermoscan Inc., CA, USA; Diatek® model 9000, Diatek Inc, CA, USA). All ITT instruments were used at the "surface mode" setting which gave the actual temperature of the surface scanned. The ITT instruments were checked at an ambient temperature of 21°C for calibration against a calibrated quartz thermometer (Hewlett Packard 2804A) and found to be accurate to 0.1°C, which is also the resolution of the instruments. The measurements were performed by the same investigator using only one ITT instrument for each trial. Data collected with the ITT instruments were recorded by the same investigator every 5 minutes during the immersions by using one randomly selected instrument per trial.

Procedures. The subjects were cooled on three occasions separated by a week. Two of the three immersions were done in conjunction with the evaluation of the Res-Q-Air inhalation system (see Ducharme et al., 1995), and the third immersion was a repetition of the control trial. Before the immersion in water, the subjects were instrumented with i) a disposable and sterile rectal probe, ii) a disposable and sterile esophageal probe, iii) ECG leads for continuous cardiac monitoring, and iv) an ear canal temperature probe in the left ear. The subject was then lifted by a crane while sitting on a nylon harness and lowered into the cold water bath for an average of 25 minutes. The temperature of the water upon entry was approximately 20°C. Following entry, ice was added to the stirred water to lower the temperature of the water to approximately 8-10°C.

Testing ITT instruments in the cold. This evaluation was comprised of three separate experiments. The protocols evolved over time as a consequence of the findings in each successive experiment. Common to all experiments, however, was the condition that the ITTs were set to surface mode and that the "tympanic target" (control) was a 50 mm diameter temperature-controlled black body disk. This disk was set to a temperature of about 37°C but the actual surface temperature was read with an infrared thermographic system (Thermovision 400 series, Agema Infrared Systems Ltd). ITT readings of the target were taken by bringing the ITT instrument to within 3 mm of the disk surface to avoid the sensor "seeing" a cool background. Previous testing had established that the angle of view of the ITTs was about 90° (Frim and Ducharme, 1994).

The first experiment was performed to determine ITT performance at an ambient temperature of 4°C. The target was set up in a temperature-controlled cold room and allowed to stabilize for about 30 minutes. Stability was verified with thermography. The ITTs were then brought into the cold room at the same time and readings of the target disk

were obtained at various intervals. The instruments were left on a bench top in the cold room between readings.

The second experiment was conducted in a cold chamber at an ambient temperature of -19°C. Again, the target disk was set to a temperature of about 37°C, and thermography verified that the disk temperature after stabilization was indeed constant (37.9–37.7°C over 40 min). Based on the previous test, it was anticipated that the ITT instruments would likely fail shortly after being brought into the cold room. Therefore, the instruments were taken into the chamber under a parka at staggered time intervals to permit several readings to be taken with the instrument over the first few minutes of exposure.

The third experiment was conducted to see what the short term response of the ITTs would be (i.e., how much time does the user need to obtain a reading). Accordingly, the instruments were tested serially, each one being taken into the cold chamber (-20°C) under a parka and readings recorded as fast as possible from the digital display over a 30 s period. The instruments were then returned to a warm ambient environment (21°C) for 30 minutes before being tested again.

According to the specifications provided by the ITT manufacturers, the lower operating temperature was 15.6°C for the FirstTemp Genius® model 3000A, 16.0°C for the Thermoscan® model IR-1, and 17.8°C for the Diatek® model 9000.

Data analyses: T_{ty} measured by three brands of ITTs were compared to the other core estimates by using a two-factor (ITT brands, temperature sites) repeated-measures analysis of variance (SuperAnova Statistical Program for General Linear Modeling, Abacus Concepts Inc., Berkeley, CA, 1989). When a significant effect was found ($p < 0.05$), a mean contrast test was used to locate significance between the means using the Greenhouse-Geisser adjusted p-value. Results are reported as means \pm SE and differences were considered significant when $p < 0.05$.

RESULTS

Tympanic temperature measurements with ITTs. Figures 1 to 3 present the comparison of the tympanic temperature readings using the ITT instruments against the other core temperature readings (T_{es} , T_{re} , T_{ear}). A significant temperature difference was found between T_{ty} and three other core temperature estimates. On average, for the three ITT instruments over the cooling phase period, T_{ty} was $0.94 \pm 0.18^\circ\text{C}$ lower than T_{es} (Genius®: $1.65 \pm 0.34^\circ\text{C}$; Diatek®: $0.57 \pm 0.24^\circ\text{C}$; Thermoscan®: $0.47 \pm 0.19^\circ\text{C}$),

Diatek®: $0.65 \pm 0.21^\circ\text{C}$, Thermoscan®: $0.72 \pm 0.15^\circ\text{C}$). The differences between *Tty* and the three core temperatures (*Tes* - *Tty*; *Tear* - *Tty*; *Tre* - *Tty*) were not different from each other. The three differences were, however, significantly larger for the Genius® ITT (*Tes* - *Tty*: 1.50 ± 0.36 ; *Tear* - *Tty*: $1.42 \pm 0.38^\circ\text{C}$; *Tre* - *Tty*: 1.54 ± 0.33) when compared to the two other instruments, but no difference was found between the Diatek® (*Tes* - *Tty*: $0.58 \pm 0.24^\circ\text{C}$; *Tear* - *Tty*: 0.67 ± 0.19 ; *Tre* - *Tty*: 0.65 ± 0.21) and the Thermoscan® instruments (*Tes* - *Tty*: 0.54 ± 0.21 ; *Tear* - *Tty*: 0.60 ± 0.20 ; *Tre* - *Tty*: 0.74 ± 0.18).

Testing ITT instruments in the cold. The results of Experiment 1 (4°C ambient temperature) are presented in Figure 4. Apart from a small 0.1°C dip at 7 min, the temperature-controlled disk maintained a very steady temperature of 36.6°C throughout the test.

Only the Genius® ITT was able to provide readings for a period of 30 minutes, with the Thermoscan® and Diatek® instruments failing to provide readings after 5 and 7 minutes, respectively. Prior to failing, the temperature readings from both instruments began $4\text{--}5^\circ\text{C}$ below the target temperature and climbed rapidly over the first few minutes.

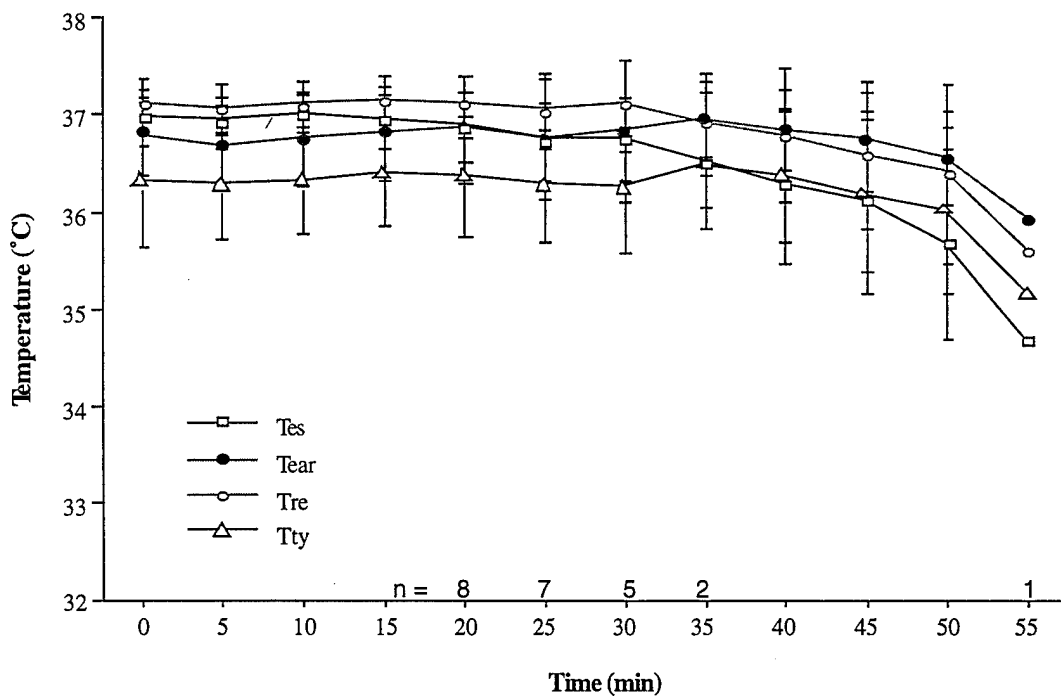


Figure 1. Mean tympanic temperature (*Tty*) measured during the water immersions with the Thermoscan® ITT compared to the other core sites (*Tes*, *Tre* and *Tear*). $n=8$, mean \pm SE.

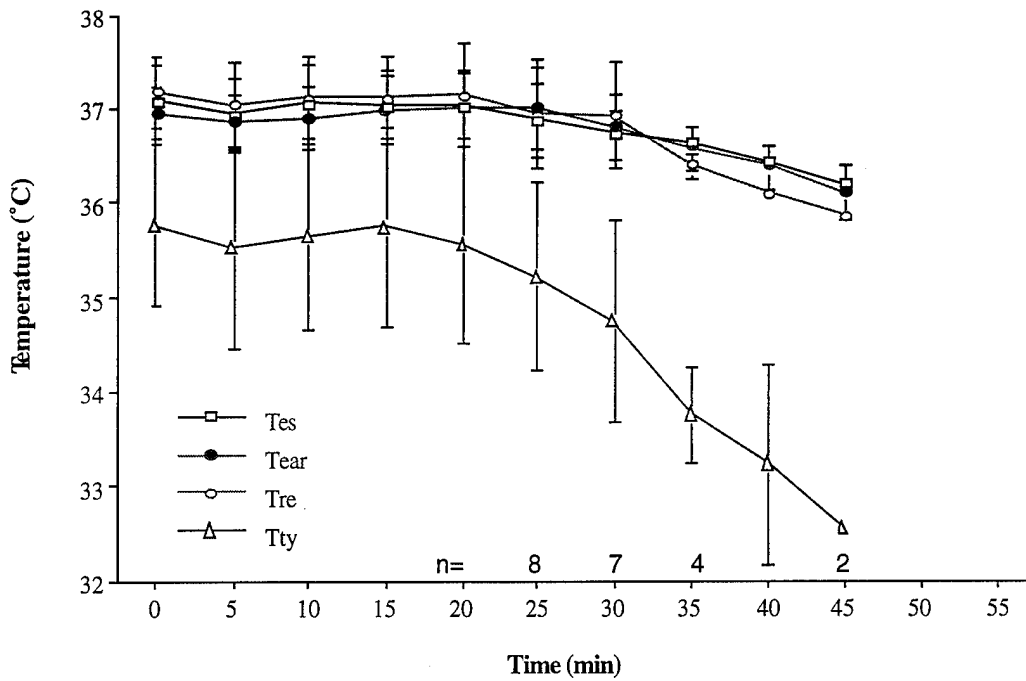


Figure 2. Mean tympanic temperature (*Tty*) measured during the water immersions with the Genius® ITT compared to the other core sites (*Tes*, *Tre* and *Tear*). $n=8$, mean \pm SE.

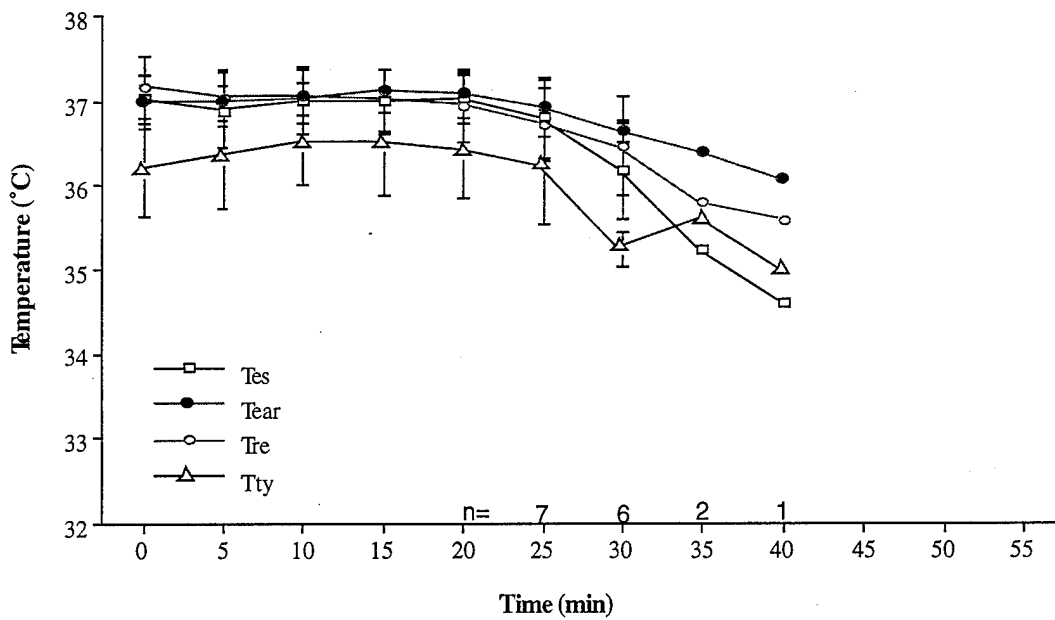


Figure 3. Mean tympanic temperature (*Tty*) measured during the water immersions with the Diatek® ITT compared to the other core sites (*Tes*, *Tre* and *Tear*). $n=8$, mean \pm SE.

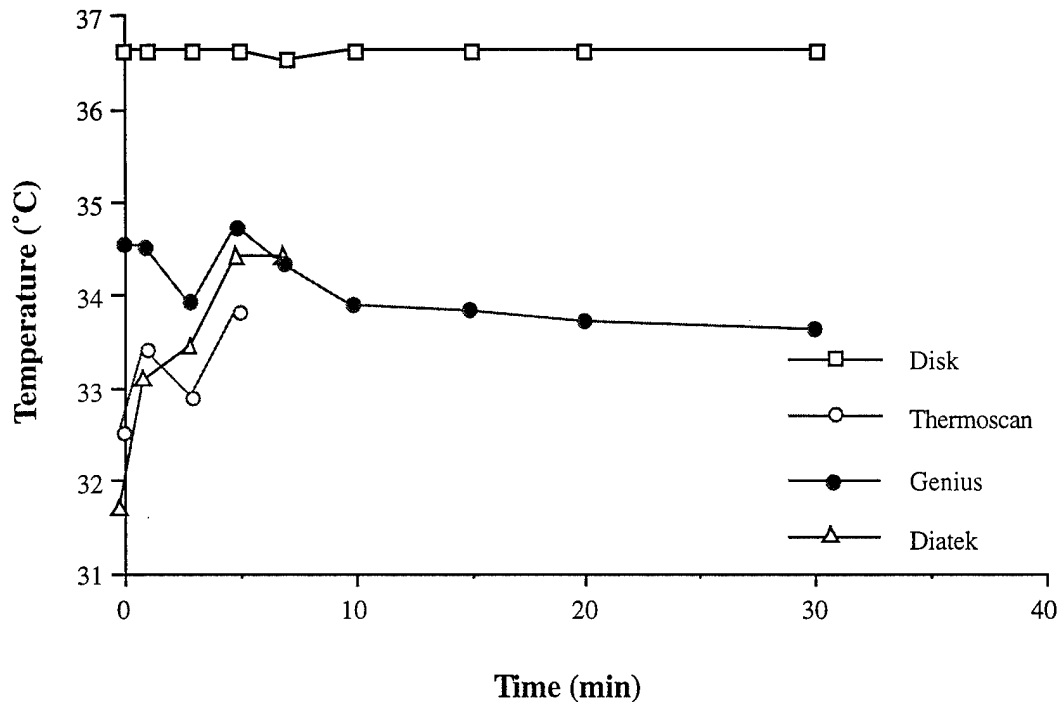


Figure 4. Temperature readings of the temperature-controlled target disk surface obtained from three ITTs as a function of time at an ambient temperature of 4°C. The data labeled "Disk" are the surface temperature of the target as measured by thermography.

By comparison, the Genius[®] ITT began only 2°C below the target temperature, showed some possible transitory instability for about 5 min, and then went into a slow decline over the remaining 25 minutes of the test. However, no instrument was able to provide an acceptable reading of the target temperature, nor was the reading stable to within 0.1°C, which would be considered a minimum requirement for acceptable performance.

The first instrument tested in Experiment 2 was the Genius[®], and the results are presented in Figure 5. Note that the first reading was about 3°C low, but the next few readings climbed rapidly, reaching a high peak reading of 52.4°C at 4 minutes. Thereafter, the readings declined smoothly over time, stabilizing 7°C below the target temperature after 30 minutes. Note also that the Genius[®] was not placed back under the parka between readings (see below) and was, therefore, exposed to -19°C conditions for the 40 minutes of the test. As was the case at -4°C, the Thermoscan[®] and Diatek[®] instruments were generally unable to provide multiple readings over time. In fact, it was only possible to obtain one reading before failure of the instruments, and these readings were about 4°C low. On the chance that operationally a user might be satisfied with a single reading, the ITT under test was replaced under the parka for 5 min before being reused. Despite this period of rewarming, readings were still 3–4°C below the true target temperature.

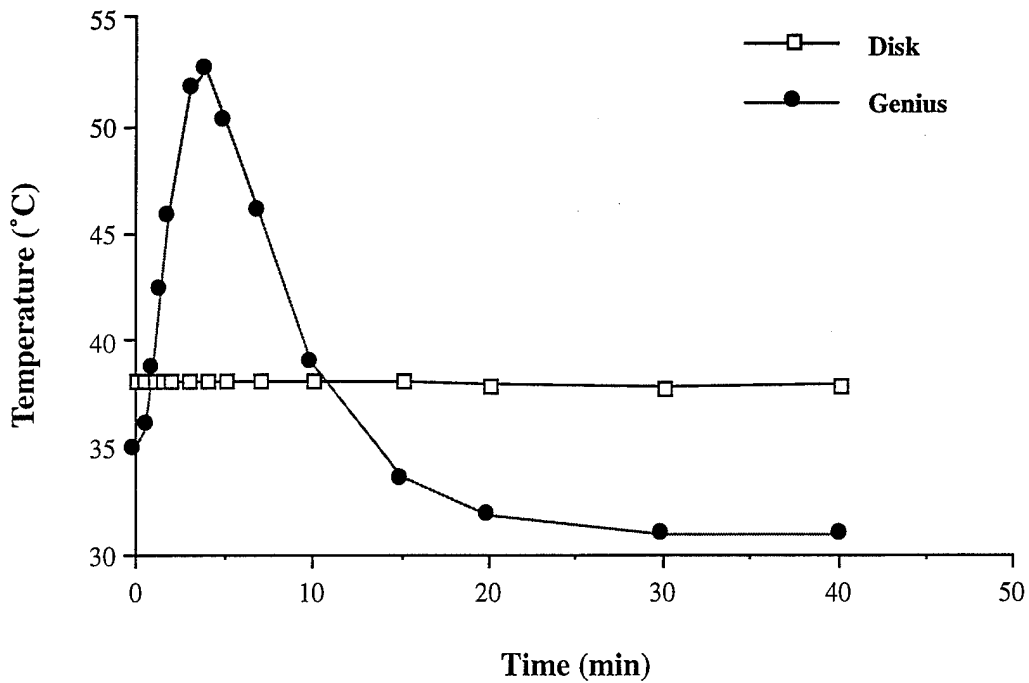


Figure 5. Temperature readings of the temperature-controlled target disk surface obtained with the Genius® ITT as a function of time at an ambient temperature of -19°C. The other two ITTs failed to perform beyond one reading. The data labeled "Disk" are the surface temperature of the target as measured by thermography.

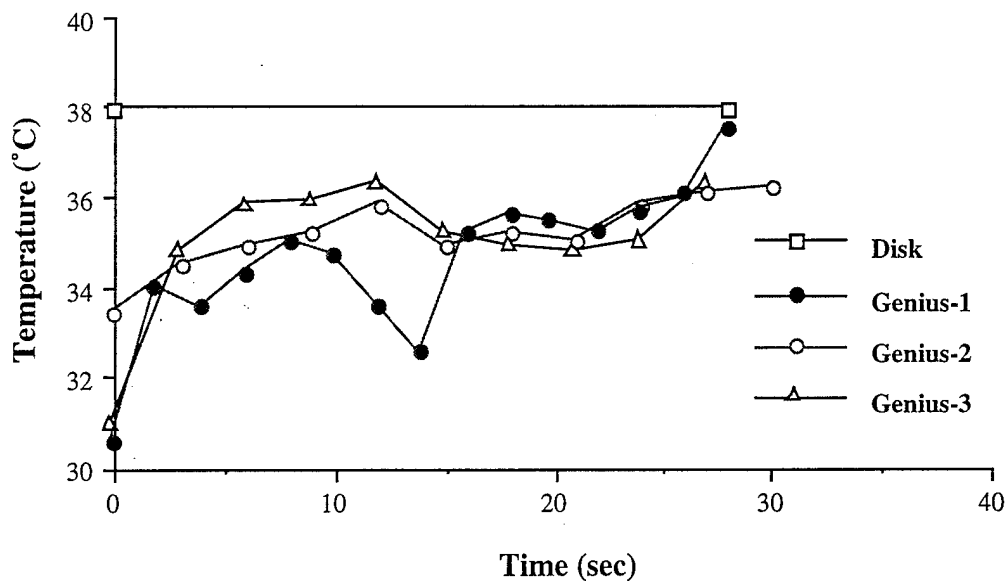


Figure 6. Temperature readings of the temperature-controlled target disk surface obtained with the Genius® ITT during the first 30 sec of exposure to an ambient temperature of -19°C. The instrument was rewarmed at room temperature for 30 min between replicate tests. The data labeled "Disk" are the surface temperature of the target as measured by thermography.

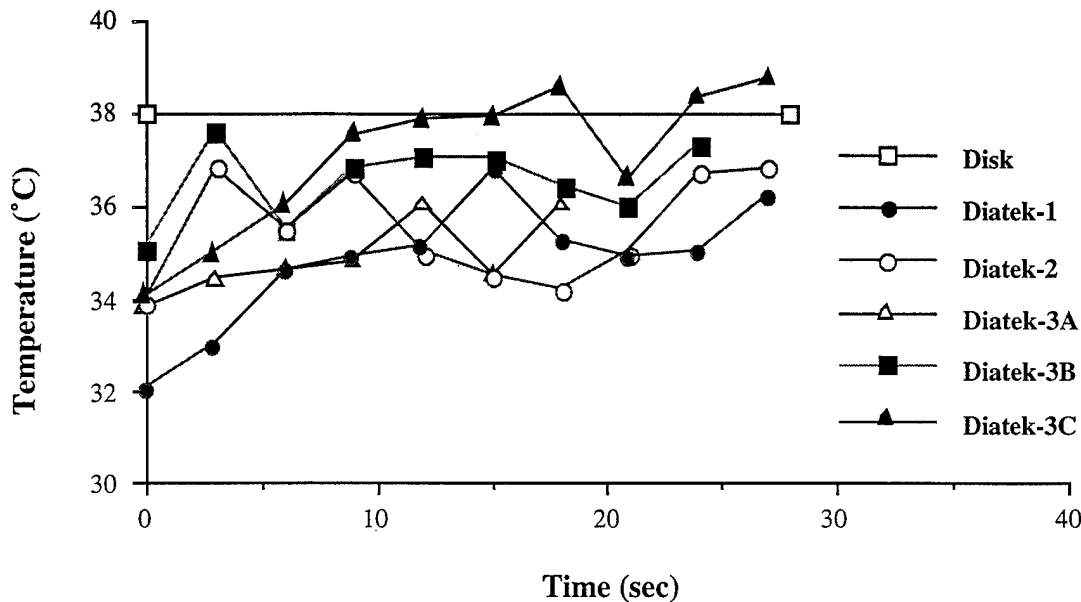


Figure 7. Temperature readings of the temperature-controlled target disk surface obtained with the Diatek® ITT during 30 sec of exposure to an ambient temperature of -20°C. The instrument was rewarmed at room temperature for 30 min between replicate tests 1–3, but tests 3A–3C were obtained in rapid succession over 2 min by successfully reactivating the instrument at -20°C without rewarming. The data labeled “Disk” are the surface temperature of the target as measured by thermography.

Interestingly, the Thermoscan® ITT only provided a single reading each time it was removed from under the parka whereas the Diatek® responded quite erratically. That is, when first tested, it only provided readings for one 30-s interval after activation (essentially one reading). However, after being rewarmed under the parka for 5 minutes, it could be activated sequentially for a total of four times (approximately 2 min of reading time). The indicated temperature rose gradually over this period but was still 2°C low when the device finally failed.

Figure 6 shows results of Experiment 3. In three replicate tests, the Genius® ITT responded with a fairly rapid increase in the indicated temperature over the first 10 s, a decrease over the next 10 sec, followed by another rise in temperature. From Experiment 2 above, this rise presumably continues toward the large peak shown in Figure 5.

Figure 7 shows the results with the Diatek® ITT. In two of the three trials, reactivating the instrument did not allow more readings to be obtained. However, on the third trial, the Diatek® instrument was able to be reactivated three times in succession (curves 3A, 3B, 3C) to provide about 90 s of data. Interestingly, the three consecutive samplings did not form a continuous set of data so they are presented as individual curves.

The Thermoscan® ITT was only able to provide a single reading each time it was tested, so the results are not presented over time. Readings were generally 4°C lower than the target temperature.

DISCUSSION

Tympanic temperature measurements with ITTs. On average for the three ITT instruments, we observed that T_{ty} was $0.99 \pm 0.18^{\circ}\text{C}$ lower than the other core estimates when measured on mildly hypothermic subjects during the cooling phase. The results are in agreement with the difference between T_{ty} and oral temperature of $0.92 \pm 0.05^{\circ}\text{C}$ reported for normothermic subjects by Ducharme et al. (1994) for the same three ITT instruments. These results, however, contrast with those of Mekjavic et al. (1992) who reported that the FirstTemp Genius® ITT provides an adequate measure of core temperature in hypothermic subjects, although they observed temperature differences as high as 0.61°C between T_{ty} measured with ITT and T_{re} . In the study of Mekjavic et al. (1992), the instrument was set to "core" or "rectal" modes as opposed to the "surface" mode used in the present study (Mekjavic, personal communication). It was observed by Frim and Ducharme (1994) that when ITTs are set to modes other than "surface", a mathematical algorithm converts the actual surface temperature read by the sensor into a value that might be obtained using conventional thermometry at a different deep body temperature site such as the mouth ("oral" mode), pulmonary artery or esophagus ("core" mode), or the rectum ("rectal" mode). The algorithms are generally based on statistical relationships between data obtained in clinical settings, and they can have restrictions. Furthermore, Frim and Ducharme (1994) observed that the mathematical algorithms varied between instruments and as a function of both target temperature and mode setting. The displayed temperature can be as much as 1.3°C above the temperature actually read by the sensor. The authors also questioned the validity of applying a fixed mathematical expression to the variable and dynamic relationships between the various deep body temperature sites.

The infrared sensor of an ITT will register the temperature of the aural structure that it can "see" during the measurement. Several factors have been identified by Ducharme et al. (1994) to significantly affect the sensor's view: the diameter of the probe tip which depends on the brand of ITT used, the technique of measurement which depends on the aiming and pressure applied by the investigator, and the characteristics of the ear canal such as the curvature, length, and presence of tympanic inflammation. These factors can more

or less contribute to the contamination of the real tympanic temperature. It was observed in the present study and by Ducharme et al. (1994) that a significantly larger difference exists between T_{ty} and the other core estimates for the Genius® ITT when compared to the two other brands. This is attributed to the larger cone-shaped head of the Genius® ITT which precludes it penetrating deep into the subject's ear canal. Ducharme et al. (1994) also reported that when subjects have ear canal characteristics deviating from the ideal ear canal for tympanic temperature measurement using an ITT (i.e. short, straight and large ear canal diameter, and absence of cerumen and inflammation), the ITT instrument cannot provide a reliable measurement of the tympanic temperature. In the present study, none of the subjects had ideal ear canal anatomy, the majority having average diameter and length with curved ear canal, and between 0 and 20% of cerumen coverage. The ITT instruments, therefore, probably did not have an ideal view of the subject's tympanum, and this can explain part of the difference in temperature between T_{ty} readings and the other core estimates.

Testing ITT instruments in the cold. Of the three ITTs tested in this study, only the Genius® provided readings when used below the minimum ambient temperature limit specified by the manufacturer. The Thermoscan® instrument generally failed to provide readings, while the Diatek® sometimes provided an error code that indicated too cold an ambient temperature. This suggests that at least one of the instruments actually reads the ambient temperature. Given the large over-indication of the Genius® in the second experiment, it is not unreasonable to conclude that ambient temperature may be sensed in all instruments and possibly used in some way to compensate for the temperature of the infrared sensor itself. In the case of the Genius®, perhaps the ambient temperature sensor responds faster to changes in ambient conditions than the infrared sensor, resulting in the instrument applying a correction factor that is greatly in error. Regardless of how ambient temperature is actually used in the ITT, the devices are not able to apply the information correctly, and no instrument is able to provide reliable readings under these cold conditions.

Performing these experiments highlighted another operational problem with using ITTs, especially in the cold. Two of the instruments provide a display that can be monitored visually while taking a reading in the ear. This feedback allows the operator to maneuver the instrument so that it sees the warmest target in the ear, which will presumably be the most correct indicator of deep body temperature. In contrast, the third instrument can only be read after removing the sensor from the ear canal because the display is on the front of the device. This makes it difficult to judge the accuracy of the aim in the ear. In the present experiments, difficulty in aiming the sensor was precluded because the target

filled the entire field of view of the instrument. Despite this, the readings of all instruments were quite variable, and user judgment was often required to “mentally average” the data over at least a few seconds. The third experiment demonstrated unequivocally that the readings are quite erratic even over short intervals.

All experiments demonstrated quite clearly that ITTs cannot provide reliable indications of deep body temperature when used in cold ambient conditions. The manufacturers claim an accuracy of $\pm 0.1^{\circ}\text{C}$, and that is the minimum acceptable variation for the intended use of the instruments. The present results show variations of up to 7°C in the short term, and as much as 14°C over longer intervals of cold exposure of the instruments. Even keeping the instruments warm under a parka and exposing them to cold only for the brief interval required to obtain a reading does not provide the required accuracy for the intended purpose.

RECOMMENDATIONS

Tympanic temperature measurements with ITTs. Based on the results of the present study in testing ITT instruments on mildly hypothermic subjects, we cannot recommend the use of the present ITT instruments to diagnose the thermal status of hypothermic victims in the field. On average, ITTs underestimate core temperature by about 1°C . The ITTs are clinical instruments with limitations regarding their accuracy in correctly reading tympanic temperature. We firmly believe, however, that the ITT technology is promising but design modifications are necessary to make them perform adequately in the field for the diagnosis of thermally injured victims.

Testing ITT instruments in the cold. ITTs cannot be recommended for use in the field for the determination of deep body temperature if ambient temperatures are below the minimum limit recommended by the manufacturer (usually 16°C). Some instruments will simply not respond, while others will give readings that are greatly in error.

It is noteworthy that the magnitude of the error is time dependent, indicating that the instruments probably use ambient temperature information to modify the raw infrared temperature data. This time dependency of the error further suggests that the ambient temperature sensor and the infrared sensor have different thermal time constants. Therefore, ITTs should be allowed to equilibrate thermally to the ambient temperature before being used even within the usable range.

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